

PATENT APPLN. NO. 10/053,915
RESPONSE UNDER 37 C.F.R. §1.111

**PATENT
NON-FINAL**

REMARKS

Claim 1 has been amended for clarity and, specifically, to recite that the cylindrical needle hub cover provided on the distal end of the needle hub has an inner channel for accommodating the needle and the needle tip protection part therein. This recitation is consistent with the recitation in claim 2 that the needle protector is movable from a position where said needle tip protection part is arranged in the inner channel of the needle hub cover before protection of the needle tip to a position where the needle tip is accommodated in the needle tip protection part for protecting the needle tip.

New claims 11 and 12 have been added to the application to recite, respectively, that the needle protector is formed of a thermoplastic material having moderate flexibility and that the thermoplastic material having moderate flexibility is selected from polypropylene, polycarbonate, acrylonitrile-butadiene-styrene copolymer, polystyrene, polyethylene and polyacetal. These limitations are supported in the specification on page 11, line 19, to page 12, line 2.

In the Action, Claims 1-4, 6 and 10 are rejected under 35 U.S.C. §103(a) as being unpatentable over Bressler et al. (U.S. Patent No. 5,466,223) ("Bressler") and claims 5 and 7-9 are

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indicated to be allowable if rewritten in proper independent form. Applicants note the indication of the allowability of claims 5 and 7-9 with appreciation. However, these claims have been maintained in dependent form because Bressler is believed to be insufficient to support a case of prima facie obviousness under 35 U.S.C. § 103(a) of claims 1-4, 6 and 10.

The position of the Office in the Section 103(a) rejection is that the needle assembly of Bressler includes each of the limitations of claim 1 (and claims 2-4, 6 and 10) except that the needle hub cover is not cylindrical. Modifying the needle assembly of Bressler to provide a cylindrical hub cover is stated to be obvious. The position of the Office is not correct. The needle assembly of Bressler does not meet the limitations of claim 1 that: (1) the cylindrical needle hub cover provided on the distal end of the needle hub have an inner channel for accommodating the needle and the needle tip protection part therein; and (2) the needle hub and the needle hub cover each have such a shape as to form, when the needle hub and the needle hub cover are joined, a side hole providing communication between the outside of said assembly and the inner channel of the needle hub cover.

Regarding the limitation (1), the guide element 31 of the needle assembly of Bressler, which corresponds to the needle hub

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cover of the needle assembly of the present invention, has two apertures, one for the barrier arm and another for the needle cannula.

On the other hand, the needle hub cover of the present invention has one aperture for accommodating both the needle and the needle tip protection part as shown in Fig. 1.

Regarding limitation (2), the needle hub and the guide element 31 of Bressler do not form, when the guide element is connected to the needle hub, a side hole providing communication between the outside of said assembly and an inner channel of the guide element.

It is also noted that the needle tip protection part of the needle assembly of the present invention can be accommodated with the needle in the channel of the needle hub cover because the needle protector including the needle tip protection part is formed of a material having moderate flexibility (as now recited in claims 11 and 12). The protector is positioned on the periphery of the syringe in the first retracted position as shown in Fig. 1, but it is positioned as abutting on the needle in the second extended position. If the protector is not flexible, it cannot be translocated from the first position to the second position in the present invention. Bressler does not disclose the use of a material having moderate flexibility as the barrier arm.

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For the above reasons, removal of the 35 U.S.C. § 103(a) ground of rejection is in order and is respectfully solicited.

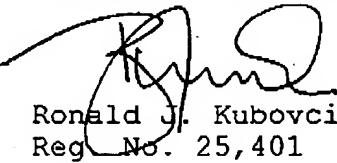
The foregoing is believed to be a complete and proper response to the Office Action dated April 13, 2004, and is believed to place this application in condition for allowance. If, however, minor issues remain that can be resolved by means of a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number indicated below.

In the event that this paper is not considered to be timely filed, applicants hereby petition for an appropriate extension of time. The fee for any such extension may be charged to our Deposit Account No. 111833.

In the event any additional fees are required, please also charge our Deposit Account No. 111833.

Respectfully submitted,

KUBOVCIK & KUBOVCIK


Ronald J. Kubovcik
Reg. No. 25,401

Atty. Case No. NPR-090
The Farragut Building
Suite 710
900 17th Street, N.W.
Washington, D.C. 20006
Tel: (202) 887-9023
Fax: (202) 887-9093
RJK/cfm